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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,702	09/13/2001	Edward A. Berger	4239-60771	9274

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	5

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,702	BERGER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, 23-24, 26-32, 48-49 and 52-55, drawn to bispecific fusion proteins wherein the first binding domain comprises the binding domain of an antibody and compositions and kits comprising said proteins.

Group II, claim(s) 1, 10-12, 26-32, 48-49 and 52-55, drawn to bispecific fusion proteins wherein the first binding domain comprises is derived from CD4 and compositions and kits comprising said proteins.

Group III, claim(s) 1, 13-18, 25-32, 48-49 and 52-55, drawn to bispecific fusion proteins wherein the second binding domain comprises the binding domain of an antibody and compositions and kits comprising said proteins.

Group IV, claim(s) 19-22, 26-32, 48-49 and 52-55, drawn to bispecific fusion proteins wherein the first binding domain comprises an HIV co-receptor or fragments thereof and compositions and kits comprising said proteins.

Group VI, claim(s) 33-34 and 37, drawn to bispecific fusion proteins comprising sCD4, scFv(17b) and a linker.

Group VII, claim(s) 35-36, drawn to nucleic acids encoding fusion proteins comprising sCD4, scFV917b) and a linker (SEQ ID NO:3).

Group VIII, claim(s) 38 and 40, drawn to nucleic acids encoding bispecific fusion proteins wherein the first binding domain comprises the binding domain of an antibody.

Group IX, claim(s) 38 and 40, drawn to nucleic acids encoding bispecific fusion proteins wherein the first binding domain comprises is derived from CD4.

Group X, claim(s) 38 and 40, drawn to nucleic acids encoding bispecific fusion proteins wherein the second binding domain comprises the binding domain of an antibody.

Group XI, claim(s) 38 and 40, drawn to nucleic acids encoding bispecific fusion proteins wherein the first binding domain comprises an HIV co-receptor or fragments thereof.

Group XII, claim(s) 39 and 40, drawn to nucleic acids encoding bispecific fusion proteins having the sequence of SEQ ID NO:4.

Group XIII, claim(s) 41-43, drawn to methods of producing bispecific fusion proteins *in vitro*.

Group XIV, claim(s) 44, drawn to a method of inactivating a gp120 protein.

Group XV, claim(s) 45, drawn to method of neutralizing a human immunodeficiency virus.

Group XVI, claim(s) 46, drawn to method of blocking the binding of gp120 to CD4.

Group XVII, claim(s) 47 and 50, drawn to method of inhibiting HIV virus replication or infectivity in a subject.

Group XVIII, claim(s) 51, drawn to a protein analog, derivative or mimic of a bispecific fusion protein wherein the first binding domain of said fusion protein comprises the binding domain of an antibody.

Group XIX, claim(s) 51 drawn a protein analog, derivative or mimic of a bispecific fusion protein wherein the first binding domain of said fusion protein is derived from CD4.

Group XX, claim(s) 51, drawn to a protein analog, derivative or mimic of a bispecific fusion protein wherein the second binding domain of said fusion protein comprises the binding domain of an antibody.

Group XXI, claim(s) 51, drawn to a protein analog, derivative or mimic of a bispecific fusion proteins wherein the second binding domain of said fusion protein comprises an HIV co-receptor or fragments thereof.

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited **product**, bispecific fusion proteins wherein the first binding domain comprises the binding domain of an antibody and compositions and kits comprising said proteins. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a

special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention. Moreover, bispecific proteins as recited in claim 1 is known in the art at the time of the invention (see Bosslet et al. U.S. Patent 5,591,828 and/or Fanger EP 0 739 904).

It should be noted that claims 1, 26-32, 38, 40, 48-49 and 51-55 are included in multiple groups. Said claims will be examined to the degree they read on the invention elected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
June 18, 2003